

**REMARKS**

No amendments are made. Claims 1-26 and 28-31 are canceled. Claims 27 and 32-45 are pending.

**Allowed Claims**

Applicants thank the Examiner for the indication that claims 27 and 32-43 are allowed.

**Rejection Under 35 U.S.C. § 112, 2<sup>nd</sup> Paragraph**

Claims 44 and 45 are rejected due to the “recitation of “or a functionally equivalent subfragment”, given that it is unclear what function is intended, and therefore it is unclear what would be functionally equivalent” (Office Action, page 2).

As stated in the specification, “the invention encompasses more than the specific exemplary nucleotide or amino acid sequences and includes functional equivalents thereof” (page 7, lines 26-28). Applicants note that claims 44 and 45 require “the isolated polynucleotide of Claim 27 or a functionally equivalent subfragment thereof” or the “isolated nucleic acid fragment of Claim 27 or a functionally equivalent subfragment thereof”, respectively. Applicants further note that claim 27 is directed to a nucleotide sequence encoding a polypeptide having  $\Delta^4$ -16:0-ACP desaturase activity, wherein the amino acid sequence of the polypeptide and the amino acid sequence of SEQ ID NO:2 have at least 95% sequence identity based on the Clustal alignment method, or its complement. Therefore, the functional equivalence stated in claims 44 or 45 refers to functional equivalence to a nucleotide sequence encoding a polypeptide having  $\Delta^4$ -16:0-ACP desaturase activity, wherein the amino acid sequence of the polypeptide and the

amino acid sequence of SEQ ID NO:2 have at least 95% sequence identity based on the Clustal alignment method, or its complement. Applicants request reconsideration of the rejection in view of the clear statement in claims 44 and 45 of the intended function.

**Rejection Under 35 U.S.C. § 112, 1<sup>st</sup> paragraph: Written Description**

Claims 44 and 45 are rejected for failing to comply with the written description requirement. The Examiner states that “the specification fails to provide a description by function or structure of any functionally equivalent subfragments” (Office Action, page 3). The Examiner further states that “to define the claimed genus the function must be identified along with the particular structural features that would confer that function” (Office Action, page 3).

Applicants respectfully disagree that the specification fails to provide a description by function or structure. With respect to function, the subfragments as claimed must be functionally equivalent to a nucleotide sequence according to claim 27, where claim 27 is directed to an isolated polynucleotide comprising: (a) a nucleotide sequence encoding a polypeptide having  $\Delta^4$ -16:0-ACP desaturase activity, wherein the amino acid sequence of the polypeptide and the amino acid sequence of SEQ ID NO:2 have at least 95% sequence identity based on the Clustal alignment method, or (b) the complement of the nucleotide sequence of (a).

With respect to structure, the specification states:

As used herein, “substantially similar,” in the case of nucleic acid fragments, refers to changes in one or more nucleotide bases that result in substitution of one or more amino acids, but do not affect the functional properties of the polypeptide encoded by the nucleotide sequence. “Substantially similar” also refers to nucleic acid fragments wherein changes in one or more nucleotide bases does not affect the ability of the nucleic acid fragment to alter gene expression patterns by gene silencing through for example antisense or co-suppression technology. “Substantially similar” also refers to modifications of the nucleic acid fragments

of the instant invention such as deletion or insertion of one or more nucleotides that do not substantially affect the functional properties of the resulting transcript vis-à-vis the ability to mediate gene silencing or alteration of the functional properties of the resulting protein molecule. It is therefore understood that the invention encompasses more than the specific exemplary nucleotide or amino acid sequences and includes functional equivalents thereof. The terms “substantially similar” and “corresponding substantially” are used interchangeably herein.

The specification further states that:

For example, it is well known in the art that antisense suppression and co-suppression of gene expression may be accomplished using nucleic acid fragments representing less than the entire coding region of a gene, and by using nucleic acid fragments that do not share 100% sequence identity with the gene to be suppressed. Moreover, alterations in a nucleic acid fragment which result in the production of a chemically equivalent amino acid at a given site, but do not effect the functional properties of the encoded polypeptide, are well known in the art. Thus, a codon for the amino acid alanine, a hydrophobic amino acid, may be substituted by a codon encoding another less hydrophobic residue, such as glycine, or a more hydrophobic residue, such as valine, leucine, or isoleucine. Similarly, changes which result in substitution of one negatively charged residue for another, such as aspartic acid for glutamic acid, or one positively charged residue for another, such as lysine for arginine, can also be expected to produce a functionally equivalent product. Nucleotide changes which result in alteration of the N-terminal and C-terminal portions of the polypeptide molecule would also not be expected to alter the activity of the polypeptide. Each of the proposed modifications is well within the routine skill in the art, as is determination of retention of biological activity of the encoded products.

(Specification, page 7, line 16 through page 8, line 19). Specifically, the specification states that changes “which result in substitution of one negatively charged residue for another, such as aspartic acid for glutamic acid, or one positively charged residue for another, such as lysine for arginine, can also be expected to produce a functionally equivalent product” (page 8, lines 12-15).

Therefore, considering the function as indicated in claim 27, and the structure as indicated in the specification as cited above, the specification clearly includes an identification of the structure and function of the functionally equivalent subfragments of claims 44 and 45 in accordance with the requirements for written description.

**Rejection Under 35 U.S.C. § 112, 1<sup>st</sup> paragraph: Enablement**

Claims 44 and 45 are rejected because the specification “does not reasonably provide enablement for a functionally equivalent fragment thereof” (Office Action, page 4). The Examiner states that the “particular sequences required to confer the claimed desaturase activity is highly unpredictable” and that the specification “lacks guidance with regard to identifying functionally active fragments, particularly given that it is unclear what function is intended” (Office Action, page 4).

In response, Applicants refer to the above arguments with respect to the required function for the functionally equivalent subfragment of either claim 44 or 45. Further, Applicants direct the Examiner’s attention to Figure 1 of the specification, which depicts an alignment of the English Ivy delta 4-16:0-ACP desaturase disclosed in the present invention and the sequence from coriander (gi: 417819) showing extensive regions of sequence identity among the plant delta 4-16:0-ACP desaturases. Applicants provide guidance on pages 7 and 8 of the specification with respect to the types of changes envisioned. For example, nucleotide changes “which result in alteration of the N-terminal and C-terminal portions of the polypeptide molecule would also not be expected to alter the activity of the polypeptide” (specification, page 8, lines 15-18). Several other possible changes are mentioned in the specification, including substitution of one negatively charged residue for another, or one positively charged residue for another

(specification, page 8, lines 10-15). Rather than being highly unpredictable as asserted by the Examiner, several changes are identified in the specification that would not be expected to alter the activity of the polypeptide.

### CONCLUSION

Based on the foregoing remarks, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 44 and 45 and allowance of this application.

### AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. 13-4500, Order No. 2119-4292. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 13-4500, Order No. 2119-4292. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

Respectfully submitted,  
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Dated: January 4, 2005

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